

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently Amended) A stabilizing catheter for protein drug delivery to a user, the stabilizing catheter comprising:

a tubing including at least one layer, wherein the at least one layer includes one or more materials that reduce diffusion of small molecules through the tubing, such that when the tubing is used for protein drug delivery, the protein drug formulation is maintained as compared with the protein drug formulation delivered via a different tubing including one or more materials that are free of an effect that reduces diffusion of small molecules through the tubing; and

wherein the one or more materials of the at least one layer includes materials selected from at least polytetrafluoroethane, saran (PVOC), polysulfone, hydrophilic glass, derivatives of these materials, and mixtures of these materials; and

wherein a protein formulation is maintained in the tubing to substantially prevent occlusions or deposits from being formed during delivery.

2. (Currently Amended) The stabilizing catheter of claim 1, wherein ~~an insulin~~ the protein formulation is maintained in the tubing to substantially prevent occlusions or deposits from being formed during an insulin delivery formulation.

3. (Currently Amended) ~~The stabilizing catheter of claim 1,~~ A stabilizing catheter for protein drug delivery to a user, the stabilizing catheter comprising:

a tubing including at least one layer, wherein the at least one layer includes one or more materials that reduce diffusion of small molecules through the tubing, such that when the tubing is used for protein drug delivery, the protein drug formulation is maintained as compared with the protein drug formulation delivered via a different tubing including one or more materials that are free of an effect that reduces diffusion of small molecules through the tubing;

wherein the one or more materials of the at least one layer includes materials selected from at least polytetrafluoroethane, saran (PVOC), polysulfone, hydrophilic glass, derivatives of these materials, and mixtures of these materials; and

wherein an insulin formulation is stabilized by being substantially free of deposits or occlusions comprising insulin and an excipient.

4. (Original) The stabilizing catheter of claim 2, wherein the insulin is a high concentration formulation.

5. (Original) The stabilizing catheter of claim 4, wherein the high concentration formulation is greater than about 100U/ml.

6. (Cancelled).

7. (Currently Amended) The stabilizing catheter of claim 1, wherein the one or more materials of the at least one layer comprises hydrophilic glass that includes glass fibers.

8. (Cancelled).

9. (Previously Presented) The stabilizing catheter of claim 1, wherein the tubing includes at least two layers.

10. (Original) The stabilizing catheter of claim 9, wherein one layer includes materials selected from at least polytetrafluoroethane, saran (PVOC), polysulfide, glass, metal, derivatives of these materials, and mixtures of these materials.

11. (Original) The stabilizing catheter of claim 9, wherein one layer includes silicone, polyurethane, derivatives of these materials or mixtures of these materials.

12. (Currently Amended) The stabilizing catheter of claim-9 11, wherein the layer including silicone, polyurethane, derivatives of these materials or mixtures of these materials is the outer layer of the tubing.

13. (Original) The stabilizing catheter of claim 9, comprising an innermost layer that is formed from one or more hydrophilic protein compatible materials.

14. (Original) The stabilizing catheter of claim 13, wherein the hydrophilic protein compatible materials are selected from at least a polyethylene glycol, a polyurethane, a Genapol, a Tween, a Triton-X and a Brij, derivatives of these materials and mixtures of these materials.

15. (Previously Presented) The stabilizing catheter of claim 9, comprising three layers, including an outer layer including a silicone material.

16. (Original) The stabilizing catheter of claim 1, wherein the small molecules have a molecular weight of about 18 g/mole to about 500 g/mole.

17. (Original) The stabilizing catheter of claim 1, wherein the small molecules include neutral molecules, charged molecules, or mixtures of these molecules.

18. (Original) The stabilizing catheter of claim 17, wherein the charged molecules include metal ions.

19. (Original) The stabilizing catheter of claim 17, wherein the neutral molecules include at least phenol, phenolic derivatives, carbon dioxide, or mixtures of these molecules.

20. (Original) The stabilizing catheter of claim 19, wherein the stabilizing catheter reduces a diffusional flow of carbon dioxide into the tubing up to about 1000 fold as compared to the diffusional flow of carbon dioxide into a different tubing that is free of a stabilizing layer.

21. (Original) The stabilizing catheter of claim 20, wherein the stabilizing catheter reduces a diffusional flow of carbon dioxide into the tubing about 10-100 fold.

22. (Original) The stabilizing catheter of claim 19, wherein the stabilizing catheter reduces a diffusional flow of phenol, phenolic derivatives, or both, out from the tubing up to about 100 fold as compared to the diffusional flow of phenol, phenolic derivatives, or both, out from a different tubing that is free of a stabilizing layer.

23. (Original) The stabilizing catheter of claim 22, wherein the stabilizing catheter reduces a diffusional flow of carbon dioxide into the tubing about 2-20 fold.

24. (Original) The stabilizing catheter of claim 19, wherein the stabilizing catheter provides a diffusional barrier to phenol and phenolic derivatives such that the loss of phenol and phenolic derivatives through the tubing is less than about 5%, +/- 1%, at an protein drug infusion rate of about 20 U/day.

25. (Previously Presented) The stabilizing catheter of claim 1, where the layer of Teflon and/or saran is about 0.002 in to about 0.02 in (about 50 to about 500 microns).

26. (Currently Amended) ~~The stabilizing catheter of claim 1,~~ A stabilizing catheter for protein drug delivery to a user, the stabilizing catheter comprising:

a tubing including at least one layer, wherein the at least one layer includes one or more materials that reduce diffusion of small molecules through the tubing, such that when the tubing is used for protein drug delivery, the protein drug formulation is maintained as compared with the protein drug formulation delivered via a different tubing including one or more materials that are free of an effect that reduces diffusion of small molecules through the tubing;

wherein the one or more materials of the at least one layer includes materials selected from at least polytetrafluoroethane, saran (PVOC), polysulfone, hydrophilic glass, derivatives of these materials, and mixtures of these materials; and

wherein the protein drug is an insulin analogue.

27. (Original) The stabilizing catheter of claim 26, wherein the insulin analogue is LISPRO.

28. – 67. (Cancelled).

68. (Currently Amended) A stabilizing catheter for protein drug delivery to a user, the stabilizing catheter comprising:

a tubing including at least one layer, wherein the at least one layer includes one or more materials that reduces the diffusion of small molecules through the tubing, such that when the stabilizing means is used for protein drug delivery, the protein drug formulation is stabilized as compared with the protein drug formulation delivered via a different tubing that includes one or more materials that are free of the effect that reduces diffusion of small molecules through the tubing; and

a hydrophilic coating on an innermost surface of the tubing formed from one or more hydrophilic protein compatible materials; and

wherein the stabilized protein drug is maintained in the tubing to substantially prevent occlusions or deposits from being formed during delivery.

69. (Currently Amended) The method of claim 68, wherein the stabilized protein drug is ~~an insulin formulation maintained in the tubing to substantially prevent occlusions or deposits from being formed during delivery.~~

70. – 86. (Cancelled).

87. (Previously Presented) The stabilizing catheter of claim 68, wherein the hydrophilic coating comprises materials applied to the innermost surface of the tubing through a surface treatment.

88. (Previously Presented) The stabilizing catheter of claim 68, wherein the hydrophilic coating composes materials applied onto the innermost surface of the tubing after the formation of the at least one layer.

89. (Previously Presented) The stabilizing catheter of claim 68, wherein the hydrophilic coating has a thickness less than that of the first layer.

90. (Currently Amended) ~~The stabilizing catheter of claim 68,~~ A stabilizing catheter for protein drug delivery to a user, the stabilizing catheter comprising:

a tubing including at least one layer, wherein the at least one layer includes one or more materials that reduces the diffusion of small molecules through the tubing, such that when the stabilizing means is used for protein drug delivery, the protein drug formulation is stabilized as compared with the protein drug formulation delivered via a different tubing that includes one or more materials that are free of the effect that reduces diffusion of small molecules through the tubing;

a hydrophilic coating on an innermost surface of the tubing formed from one or more hydrophilic protein compatible materials; and

wherein the hydrophilic protein compatible material is a polymer containing a PEG moiety.

91. (Previously Presented) The stabilizing catheter of claim 68, wherein the hydrophilic protein compatible materials are selected from at least a polyethylene glycol, a Genapol, a Tween, a Triton-X, and a Brij, derivatives of these materials and mixtures of these materials.

92. (Previously Presented) The stabilizing catheter of claim 1, further comprising a hydrophilic coating coated onto an innermost surface of the tubing formed from one or more hydrophilic protein compatible materials.

93. (Previously Presented) The stabilizing catheter of claim 92, wherein the hydrophilic coating comprises materials applied to the innermost surface of the tubing through a surface treatment.

94. (Previously Presented) The stabilizing catheter of claim 92, wherein the hydrophilic coating is applied onto the innermost surface of the tubing after the formation of the at least one layer.

95. (Previously Presented) The stabilizing catheter of claim 92, wherein the hydrophilic coating has a thickness less than that of the first layer.

96. (Currently Amended) ~~The stabilizing catheter of claim 68;~~ A stabilizing catheter for protein drug delivery to a user, the stabilizing catheter comprising:

a tubing including at least one layer, wherein the at least one layer includes one or more materials that reduces the diffusion of small molecules through the tubing, such that when the stabilizing means is used for protein drug delivery, the protein drug formulation is stabilized as compared with the protein drug formulation delivered via a different tubing that includes one or more materials that are free of the effect that reduces diffusion of small molecules through the tubing;

a hydrophilic coating on an innermost surface of the tubing formed from one or more hydrophilic protein compatible materials; and

wherein the hydrophilic protein compatible material is a polymer containing a PEG moiety.

97. (Previously Presented) The stabilizing catheter of claim 92, wherein the hydrophilic protein compatible materials are selected from at least a polyethylene glycol, a Genapol, a Tween, a Triton-X, and a Brij, derivatives of these materials and mixtures of these materials.

98. (Previously Presented) The stabilizing catheter of claim 1, wherein the tubing defines an interior volume through which a protein drug may be conveyed, and the at least one

layer comprises a wall of the tubing that separates the interior volume from an exterior of the tubing.

99. (Previously Presented) The stabilizing catheter of claim 1, wherein the tubing defines an interior volume through which a protein drug may be conveyed, the at least one layer forms a wall of the tubing that borders the interior volume of the tubing.

100. (Previously Presented) The stabilizing catheter of claim 1, wherein the tubing defines a length dimension along which a protein drug may be conveyed and wherein the at least one layer extends along substantially the entire length dimension of the tubing.

101. (Previously Presented) The stabilizing catheter of claim 10, wherein the tubing defines a length dimension along which a protein drug may be conveyed and wherein the two layers extend along substantially the entire length dimension of the tubing.